

Application No.: 10/575,870
Filing Date: April 17, 2006

AMENDMENTS TO THE CLAIMS

The listing of claims below replaces all prior versions and listings of claims. Only those claims being amended herein show their changes in highlighted form, where insertions appear as underlined text (e.g., insertions), while deletions appear as strikethrough text (e.g., ~~deletions~~) or enclosed in double brackets (e.g., [[deletion]]).

1. (Currently Amended) An apparatus for aspirating, irrigating and/or cleansing wounds, comprising: characterised in that it comprises

a) a fluid flow path, comprising:

i) a conformable wound dressing, having comprising a backing layer which is capable of forming a relatively fluid-tight seal or closure over a wound and a wound-facing face, and at least one inlet pipe for connection to a fluid supply tube, which passes passing through and/or under the wound-facing face and directly or indirectly communicating with at least a fluid reservoir, and [[and]] at least one outlet pipe for connection to a fluid offtake tube, which passes passing through and/or under the wound-facing face, wherein a relatively fluid-tight seal or closure is formed over the wound at the point at which the ~~or~~ each inlet pipe and ~~the~~ ~~or~~ each outlet pipe passes through and/or under the wound-facing face; forming a relatively fluid-tight seal or closure over the wound, at least one inlet pipe being connected to a fluid recirculation tube, at least one outlet pipe being connected to a fluid offtake tube; and

ii) a means for fluid cleansing in direct or indirect communication at least with the outlet pipe configured to retain in the cleansed fluid nutrients, molecules, factors, and/or other components from the wound exudate that aid in proliferation or that are favorable to the wound healing having at least one inlet port connected to a fluid offtake tube and at least one outlet port connected to a fluid recirculation tube; and

iii) a biodegradable scaffold located under the backing layer and configured to be placed in contact with a wound bed in use;

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a fluid recirculation tube for directing cleansed fluid from the means for fluid cleansing back into the inlet pipe so that nutrients, molecules, factors, and/or other components from the wound exudate that aid in proliferation or that are favorable to the wound healing process are returned to the wound;

b) a fluid reservoir connected by a fluid supply tube to an integer of the flow path (optionally or as necessary via means for flow switching between supply and recirculation);

c) a device for moving fluid through at least the wound dressing and means for fluid cleansing, and optionally or as necessary the fluid supply tube; and

d) a means for bleeding the fluid flow path to bleed fluid from the recirculation tube;[[,]]

the apparatus being configured such that fluid may can be supplied to fill the fluid flow path from the fluid reservoir via the fluid supply tube (optionally or as necessary via the means for flow switching) and such that at least a portion of the fluid flowing through the outlet pipe can be recirculated via the fluid recirculation tube through the fluid flow path.

2. **(Currently Amended)** An apparatus according to claim 1, wherein characterised in that the biodegradable scaffold comprises a three-dimensional mesh, sponge or felt.

3. **(Currently Amended)** An apparatus according to claim 1, wherein characterised in that the biodegradable scaffold comprises a poly(hydroxyl acid) or ester thereof selected form from the group consisting of poly(glycolic acid), poly(L-lactic acid), poly(D-lactic acid) and esters thereof, or and copolymers of and blends thereof.

4. **(Currently Amended)** An apparatus according to claim 1, wherein characterised in that the biodegradable scaffold comprises a biologically sourced biodegradable substantially protein based polymer selected form from the group consisting of collagens, fibronectins, or and fibrins, as whole molecules or derivatives thereof from proteolytic or chemical treatments, or and blends thereof, or biodegradable substantially protein based polymers selected from collagens, fibronectins, or fibrins, or fragments thereof, produced through recombinant DNA techniques, or blends thereof.

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5. (Currently Amended) An apparatus according to claim 1, characterized in that it comprises further comprising a means for fluid cleansing that is a single-phase system, in which the circulating fluid from the wound passes through the means for fluid cleansing and materials deleterious to wound healing are removed, without the circulating fluid coming into direct or indirect contact with another fluid in the means for fluid cleansing.

6. (Currently Amended) An apparatus for aspirating, irrigating and/or cleansing wounds, comprising:

a fluid flow path, comprising:

a conformable wound dressing, comprising a backing layer which is capable of forming a relatively fluid-tight seal or closure over a wound and a wound-facing face, at least one inlet pipe passing through and/or under the wound-facing face and directly or indirectly communicating with at least a fluid reservoir, and at least one outlet pipe passing through and/or under the wound-facing face, wherein a relatively fluid-tight seal or closure is formed over the wound at the point at which each inlet pipe and each outlet pipe passes through and/or under the wound-facing face; and

a means for fluid cleansing in direct or indirect communication at least with the outlet pipe;

a fluid recirculation tube for directing cleansed fluid from the means for fluid cleansing back into the inlet pipe so that nutrients, molecules, factors, and/or other components from the wound exudate that aid in proliferation or that are favorable to the wound healing process are returned to the wound; and

a biodegradable scaffold located under the backing layer and configured to be placed in contact with a wound bed in use;

a device for moving fluid through at least the wound dressing and means for fluid cleansing; and

An apparatus according to claim 1, characterized in that it comprises a means for fluid cleansing that is a two-phase system, in which the circulating fluid from the wound passes through the means for fluid cleansing and materials deleterious to wound healing

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are removed[[,]] by the circulating fluid coming into direct or indirect contact with another fluid in the means for fluid cleansing;

wherein the apparatus is configured such that fluid can be supplied to fill the fluid flow path from the fluid reservoir and such that at least a portion of the fluid flowing through the outlet pipe can be recirculated via the fluid recirculation tube through the fluid flow path.

7. **(Currently Amended)** An apparatus according to claim 6 [[3]], wherein characterised in that in the means for fluid cleansing, the circulating fluid from the wound and the other fluid in the means for fluid cleansing are separated by an integer which is selectively permeable to materials deleterious to wound healing.

8. **(Currently Amended)** An apparatus according to claim 6 [[3]], wherein characterised in that in the means for fluid cleansing, the circulating fluid from the wound and the other fluid in the means for fluid cleansing are separated by an integer which is not selectively permeable to materials deleterious to wound healing, and the other fluid comprises and/or is in contact with a material that removes materials deleterious to wound healing.

9. **(Currently Amended)** An apparatus-A conformable wound dressing assembly for use in an apparatus according to claim 1, characterized in that it comprises a dressing as recited in claim 1 and a biodegradable scaffold wherein the biodegradable scaffold comprises biodegradable substantially protein based polymers selected from the group consisting of collagens, fibronectins, fibrins, and fragments thereof, produced through recombinant DNA techniques, and blends thereof.

10. **(Previously Presented)** A method of treating wounds to promote wound healing using the apparatus for aspirating, irrigating and/or cleansing wounds according to claim 1.

11. **(New)** An apparatus according to claim 1, wherein the apparatus is configured such that at least a portion of the fluid flowing through the outlet pipe is directed to a waste reservoir.

12. **(New)** An apparatus according to claim 6, wherein the means for fluid cleansing comprises a biphasic extraction unit.

13. **(New)** An apparatus for aspirating, irrigating and/or cleansing wounds, comprising:

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a wound dressing configured to form a relatively fluid-tight seal around at least a portion of a wound;

at least one inlet pipe configured to communicate with the dressing and to provide a fluid conduit into the dressing;

at least one outlet pipe configured to communicate with the dressing and to provide a fluid conduit out of the dressing;

a biodegradable scaffold under the dressing, at least a portion of the scaffold configured to be in contact with the wound;

a fluid reservoir comprising irrigation fluid in fluid communication with the inlet pipe to supply irrigation fluid from the fluid reservoir into the dressing;

a fluid pump configured to pump fluid through at least the inlet pipe, the wound dressing, and the outlet pipe;

a fluid cleansing mechanism in fluid communication with the outlet pipe, the fluid cleansing mechanism being configured to at least reduce the amount of fluid soluble deleterious components in the fluid that flows out of the dressing; and

a recirculation tube in fluid communication with the fluid cleansing mechanism configured to recirculate fluid cleansed by the fluid cleansing mechanism into the inlet pipe so that nutrients, molecules, factors, and/or other components from the wound exudate that aid in proliferation or that are favorable to the wound healing process are returned to the wound.

14. (New) An apparatus according to claim 13, wherein the fluid cleansing mechanism comprises a single-phase cleansing system, in which the fluid that flows out of the dressing passes through the single-phase cleansing system and materials deleterious to wound healing are removed without the fluid that flows out of the dressing coming into direct or indirect contact with another fluid in the single-phase cleansing system.

15. (New) An apparatus according to claim 13, wherein the fluid cleansing mechanism comprises an ultrafiltration unit.

16. (New) An apparatus according to claim 13, wherein the fluid cleansing mechanism comprises a chemical absorption and/or adsorption unit.

17. **(New)** An apparatus according to claim 13, wherein the fluid cleansing mechanism comprises a two-phase cleansing system, in which the fluid that flows out of the dressing passes through the two-phase cleansing system and materials deleterious to wound healing are removed by directly or indirectly contacting the fluid that flows out of the dressing with another fluid in the two-phase cleansing system.

18. **(New)** An apparatus according to claim 13, wherein the fluid cleansing mechanism comprises a dialysis unit.

19. **(New)** An apparatus according to claim 13, wherein the biodegradable scaffold comprises a mesh, sponge or felt.

20. **(New)** An apparatus according to claim 13, wherein the biodegradable scaffold comprises a poly(hydroxyl acid) or ester thereof selected from the group consisting of poly(glycolic acid), poly(L-lactic acid), poly(D-lactic acid) and esters thereof, and copolymers and blends thereof.

21. **(New)** An apparatus according to claim 13, wherein the biodegradable scaffold comprises a biologically sourced biodegradable substantially protein based polymer selected from the group consisting of collagens, fibronectins, and fibrins, as whole molecules or derivatives thereof from proteolytic or chemical treatments, and blends thereof.

22. **(New)** An apparatus according to claim 13, further comprising means for bleeding the fluid flow path to bleed fluid from the recirculation tube

23. **(New)** A method of treating a wound, comprising:

providing a conformable wound dressing configured to form a relatively fluid-tight seal around at least a portion of a wound;

providing an apparatus for irrigating and/or cleansing a wound comprising:

a fluid reservoir comprising irrigation fluid;

at least one inlet pipe configured to communicate with the dressing and to provide a fluid conduit into the dressing;

at least one outlet pipe configured to communicate with the dressing and to provide a fluid conduit out of the dressing;

positioning a biodegradable scaffold under the dressing, wherein at least a portion of the scaffold is in contact with the wound bed;

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pumping fluid through at least the inlet pipe, the wound dressing, and the outlet pipe;

cleansing the fluid that flows out of the wound dressing to reduce the amount of deleterious components in the fluid that flows out of the dressing without substantially reducing the amount of the components in the fluid that flows out of the dressing that are beneficial to wound healing; and

recirculating at least a portion of the fluid that flows out of the wound dressing back to the dressing after being cleansed so that nutrients, molecules, factors, and/or other components from the wound exudate that aid in proliferation or that are favorable to the wound healing process are returned to the wound.

24. (New) The method of Claim 23, further comprising regulating the fluid that flows out of the wound dressing so that a portion of the fluid that flows out of the wound dressing is directed to a waste reservoir.

25. (New) The method of Claim 23, further comprising adjusting the proportion of the amount of fluid that is provided to the dressing after being cleansed and the amount of fluid provided to the dressing from the fluid reservoir.

26. (New) The method of Claim 23, wherein cleansing the fluid comprises at least reducing the amount of fluid soluble deleterious components in the fluid that flows out of the dressing.

27. (New) The method of Claim 23, wherein the apparatus for irrigating and/or cleansing a wound comprises a single-phase cleansing system, in which the fluid that flows out of the dressing passes through the single-phase cleansing system and materials deleterious to wound healing are removed without the fluid that flows out of the dressing coming into direct or indirect contact with another fluid in the single-phase cleansing system.

28. (New) The method of Claim 23, wherein the apparatus for irrigating and/or cleansing a wound comprises an ultrafiltration unit.

29. (New) The method of Claim 23, wherein the apparatus for irrigating and/or cleansing a wound comprises a chemical absorption and/or adsorption unit.

30. (New) The method of Claim 23, wherein the apparatus for irrigating and/or cleansing a wound comprises a two-phase cleansing system, in which the fluid that flows out of

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the dressing passes through the two-phase cleansing system and materials deleterious to wound healing are removed by directly or indirectly contacting the fluid that flows out of the dressing with another fluid in the two-phase cleansing system.

31. **(New)** The method of Claim 23, wherein the apparatus for irrigating and/or cleansing a wound comprises a dialysis unit.

32. **(New)** The method of Claim 23, wherein the biodegradable scaffold comprises a mesh, sponge or felt.

33. **(New)** The method of Claim 23, wherein the biodegradable scaffold comprises a poly(hydroxyl acid) or ester thereof selected from the group consisting of poly(glycolic acid), poly(L-lactic acid), poly(D-lactic acid) and esters thereof, and copolymers and blends thereof.

34. **(New)** The method of Claim 23, wherein the biodegradable scaffold comprises a biologically sourced biodegradable substantially protein based polymer selected from the group consisting of collagens, fibronectins, and fibrins, as whole molecules or derivatives thereof from proteolytic or chemical treatments, and blends thereof.

35. **(New)** The method of Claim 23, further comprising, bleeding at least a portion of the fluid prior to recirculating the fluid back to the dressing.